REMARKS

This is in response to the Office Action mailed November 8, 2006. Submitted herewith is a petition for a two month extension of time. Also submitted herewith is a supplemental declaration, i.e., a "Reissue Application Declaration By the Inventor". The supplemental declaration is submitted herewith because an additional inventor is being named, i.e., Gerald Gontarz. In accordance with MPEP §1412.04(II), in the case of a broadening reissue, a declaration signed by the inventors appears to be required when an additional inventor is named. Addition of Gerald Gontarz as an inventor is respectfully requested.

Applicants note that, in the Office Action mailed November 8, 2006, there was no indication that new claims 50 and 51 were considered by the Examiner. The new claims were submitted by applicant in the response dated August 7, 2006. Accordingly, if necessary, re-issuance of a new, non-final Office Action is respectfully requested to reflect consideration of claims 50 and 51.

Also submitted herewith is a "Supplemental Prior Claim Listing". Certain claims were amended in Applicants' response dated August 7, 2006. In that response, the amended claims were not marked in accordance with 37 CFR §1.173 (Reissue specification, drawings and amendments). The Supplemental Prior Claim Listing presents those claims marked in accordance with 37 CFR §1.173 (MPEP §1453).

By the present amendment, claims 1 through 38 and 40 through 51 are pending. Claim 39 has been cancelled without prejudice solely to facilitate prosecution of this application. As discussed below, Applicants do not agree with the Examiner's position with respect to the rejection of claims 39, 40, 43, 45 and 46 under 35 USC §102(b) as being anticipated by Bao et al. (US Pat. 5,534,028) and claims 39, 40 and 43-46 as being anticipated by Ray et al. (US Pat. 5,674,295).

Claims 41, 42, 48 and 49 were indicated to be allowable by the Examiner if rewritten in independent form including all the limitations of the base claim. The present amendment accomplishes that object. In particular claim 41 is amended to remove dependency from cancelled claim 39 and to incorporate the body of claim 39 into its text. In addition, claims 40 and 45-47 have been amended to remove dependency from cancelled claim 39, to depend from allowable claim 41, and should be allowable as well. No new matter has been added by the present amendment.

Turning now to aforementioned the rejections of the claims under 35 USC §102(b), at page 4 of the Office Action, the Examiner argues that, "the prior art discloses all the structural limitations entered in the claims" and that because the Bao et al. implant comprises a hydrogel capable of having a constant swell and is constrained tightly in the cavity of a disc, it is "per se, capable of expanding beyond the height of the disc cavity." Applicants disagree. It is respectfully submitted that the Bao et al. implant can be "constrained tightly" without expanding beyond the height of the disc cavity. Indeed, at column 2, lines 34-37, Bao et al. itself refutes the Examiner's argument by expressly stating that, "the nucleus comprises a biologically compatible hydrogel having when fully hydrated a size and shape generally conforming to a natural nucleus;..." (emphasis added). Nowhere does Bao et al. teach or suggest that the implant should have a capacity to swell to a second height which is greater than the height of the cavity defined between adjacent vertebrae as claimed. The Examiner's admitted "belief" is unsupported speculation and is, in reality, 20/20 hindsight, knowable only after reading applicants' specification. In essence, the Examiner's argument appears to be based on "inherency" since the concept of expansion beyond the disc height is clearly not disclosed in the Bao et al. specification *per se*. However, in order for inherent anticipation to be applicable, the inherent property (expansion beyond the disc height) must inevitably result from the structure disclosed by Bao et al. It is not inevitable that the Bao et al. implant will expand beyond the disc height, especially in view of the teaching at column 2, lines 34-37.

Similarly, nowhere in Ray et al. is there a teaching or suggestion that the implant could or should expand beyond the disc height. Indeed, at column 3, lines 23-25, Ray et al. states that, "These components reestablish near normal disc height and normal annulus position and function." Moreover, at column 6, lines 43-45, Ray et al. teaches that, "These dimensions [of the implant] conform with the approximate length of the sagittal diameter and approximate height of an adult human disc nucleus space" (emphasis added). These portions show that the Examiner's assertions are completely unsupported. Ray et al. simply fails to remedy the deficiencies of Bao et al.

Since Bao et al. or Ray et al., taken alone or in combination, neither teach nor suggest expansion of the implant beyond the disc height, the rejection under 35 USC §102(b) is improper and should be withdrawn.

Applicants also disagree with the Examiner's assertion that Bao et al. discloses anisotropic expansion based on the disclosure in Figure 14 and column 7, lines 1-6. The further assertion that "the implant is made out of two different materials, therefore the material will have isotropic movement" is unsupportable speculation. Where in the Bao et al. disclosure does it say that the two different materials do not isotropically expand? Where is it written that two different materials cannot have substantially the same expansion properties? Figure 14 shows a core 32 completely encapsulated by the stiffer gel 38. There is simply no teaching or suggestion for anisotropic expansion of such a structure. Even the structures of Figures 4, 5, and 7 do not support the position taken by the Examiner. Indeed, if the "stiffer" layer did not expand isotropically with the less stiff layer, they would delaminate from each other on repeated hydration and dehydration (similar to compression and expansion of a water-filled sponge) in operation in a disc space. Further proof of the shortcomings of the Examiner's argument can be seen from Figures 2 and 3 of Bao et al. Fig. 2 shows a dehydrated implant centrally positioned within the disc space. As can be seen, the walls of the disc space are space substantially equidistant from the sides if the implant. Fig. 3 shows that the implant has isotropically expanded in all directions to fill the disc space. As above, since there is no disclosure of

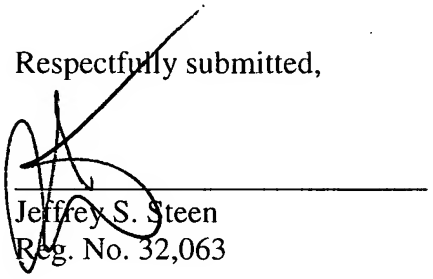
anisotropic expansion in Bao et al. *per se*, the Examiner's position is apparently based on inherent anticipation. To form a legitimate basis for such a position, anisotropic expansion would inevitably have to result from the Bao et al. implant. Figs. 2 and 3 demonstrate that such a result is not inevitable. Moreover, there is simply no basis legitimately cited by the Examiner to support the assertion that merely because one material is stiffer than another, they would not, or could not, expand isotropically together. Since Bao et al. does not teach or suggest anistropic expansion of the implant, the rejection of claims 39, 40, 43, 45 and 46 is improper and should be withdrawn.

There is also no basis in Ray et al. to assert anisotropic expansion of the implant. Indeed, the Office Action is completely conclusory in this respect. No reasoning or rationale is supplied to justify the conclusion. It is respectfully submitted that a bare, unsupported conclusory statement does not form a legitimate basis to support a rejection of claims 39, 40, and 43-46 as anticipated by Ray et al. Withdrawal of the rejection is therefore respectfully requested.

The rejection of claim 47 under 35 USC §103(a) is unsupported for at least the reasons stated above. In addition, the Examiner states that "Applicant has not disclosed that by having a xerogel material provides an advantage, is used for a particular purpose, or solves a stated problem." Again, Applicants disagree. For example, at column 11, lines 48-53, the present specification states, "Insertion shape B is the shape of xerogel deformed in such a way that it facilitates insertion and anisotropic swelling in the preferred direction of spinal axis. The xerogel in the shape B and anisotropically dehydrated state has the shape optimized for insertion into the cavity through a small incision in the annulus fibrosus" (emphasis added). Advantages of a xerogel are plainly stated. Accordingly, the rejection under 35 USC §103(a) is improper and should be withdrawn.

A good faith effort has been made to place the present application in condition for allowance. If there is any point requiring discussion prior to allowance, the Examiner is earnestly solicited to telephone the undersigned attorney for Applicants at the address below.

Respectfully submitted,



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Supplemental Prior Claim Listing

The following claims were amended in Applicants' prior response dated August 7, 2006. In that response, the amended claims were not marked in accordance with 37 CFR §1.173 (Reissue specification, drawings and amendments). Accordingly, the claims presented in that response are re-presented here with proper marking for purposes of clarification. In certain instances below, although the presentation of the amended new claims may not contain any indication of what was changed from the previous version of the claims (in accordance with MPEP §1453), resort can be made to the format of the amended claims submitted with the August 7, 2006 response, which provides a ready comparison to see what was added or deleted. Notwithstanding this Supplemental Prior Claim Listing, the listing of claims in the present Amendment Under 37 CFR §1.116 will replace all prior versions, and listings of claims in the application

1. (Amended) A spinal nucleus implant for replacement of at least a portion of nucleus pulposus tissue removed from a spinal disc of a living vertebrate to restore function of said spinal disc and related vertebral joint, and implantable into the cavity created by said removal of nucleus pulposus tissue, which comprises:

A swellable, biomimetic plastic, having a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, said biom[r]imetic plastic having an inherent shape in which it has a relaxed polymer network in a state of full hydration, having an insertion shape in which it is at least partially dehydrated to a xerogel state and formable into a compacted mode for maximum efficiency of surgical insertion, and capable of anisotropic expansion due to partial rehydration in situ into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state, said anisotropically swellable biomimetic plastic having preferred

swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes.

2. (Original) The spinal nucleus implant of claim 1 wherein said implant is anisotropically deformable in its said indwelling shape having preferred deformability in a vertical plane and suppressed deformability in horizontal planes under compression in the vertical plane.

3. (Original) The spinal nucleus implant of claim 1 wherein said swellable, biomimetic plastic is at least partially hydrated in its insertion xerogel state.

4. (Original) The spinal nucleus implant of claim 1 wherein said swellable, biomimetic plastic has been formed in a physiologically safe form by being plasticized with a non-toxic liquid in its insertion xerogel state.

5. (Amended) The spinal nucleus implant of claim 4 wherein said non-toxic liquid is present at a concentration less than 50% by weight of the plasicized anisotropica[f]lly swellable, biomim[n]etic plastic.

6. (Original) The spinal nucleus implant according to claim 3 wherein said non-toxic liquid is selected from the group consisting of glycerol, glycerol monoacetate, glycerol diacetate, glycerylformal, dimethyl sulfoxide, water and mixtures thereof.

7. (Original) The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic is a dehydrated anisotropically swellable plastic wherein both said hydrophobic phase and said hydrophilic phase each have hydrophobic and hydrophilic aspects and said hydrophobic phase is a less hydrophilic phase having higher content of hydrophobic groups and said hydrophilic phase is a less hydrophobic phase having higher content of hydrophilic groups, relative to one another.

8. (Original) The spinal nucleus implant according to claim 7 wherein said anisotropically swellable, biomimetic plastic comprises non-degradable polymer with a carbon-carbon backbone.

9. (Original) The spinal nucleus implant according to claim 7 wherein said less hydrophilic phase is a crystalline phase containing nitrile groups.

10. (Original) The spinal nucleus implant according to claim 7 wherein said hydrophilic phase has hydrophilic groups which are selected from a group consisting of hydroxyl, carboxyl, carboxylate, amide, N-substituted amide, amidine and N-substituted amidine.

11. (Amended) The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic has water content more than 70% by weight in said state of full[y] hydration by deionized water.

12. (Amended) The spinal nucleus implant according to claim 11 wherein said swellable, biomim[n]etic plastic has water content more than 95% by weight in said state of full hydration.

13. (Original) The spinal nucleus implant according to claim 1 wherein said more hydrophilic phase is substantially discrete hydrophilic domains dispersed in a substantially continuous less hydrophilic domain.

14. (Original) The spinal nucleus implant according to claim 1 wherein both the hydrophilic phase and the hydrophobic phase are substantially continuous hydrophilic domains and hydrophobic domains forming an interpenetrating network.

15. (Original) The spinal nucleus implant according to claim 1 wherein said hydrophobic phase contains crystalline polymer phase detectable by x-ray diffraction.

16. (Original) The spinal nucleus implant according to claim 7 wherein said more hydrophobic phase is substantially discrete crystalline domains dispersed in a substantially continuous more hydrophilic domain.

17. (Original) The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic has hydrophilic lubricious surface.

18. (Original) The spinal nucleus implant according to claim 17 wherein said surface is formed in a gradiented manner with increasing carboxylic groups from the center of said implant towards its outer surface.

19. (Original) The spinal nucleus implant according to claim 1 wherein said implantable device has at least the two following structural components:

a) an inner core from said swellable plastic; and,

b) an outer jacket that is surrounding said core and made from said swellable plastic which is, in its fully hydrated state, less swellable than said inner core.

20. (Original) The spinal nucleus implant according to claim 1 including at least one reinforcing element from a substantially non-swellable material embedded in said swellable, biomimetic plastic.

21. (Amended) The spinal nucleus implant according to claim 19 and further including at least one reinforcing element from a substantially non-swellable material embedded in said swellable, biomim[n]etic plastic wherein said at least one reinforcing element is located between said jacket and said core.

22. (Original) The-spinal nucleus implant according to claim 20 wherein said at least one reinforcing element is made from an implantable material selected from the group consisting of metal, metal alloys, carbon, ceramics, polymer and combinations thereof.

23. (Original) The spinal nucleus implant according to claim 22 wherein said polymer is selected from a group consisting of acrylic polymer, methacrylic polymer, polyester, polyurethane, polyurea, polyolefin, halogenated polyolefin, polysaccharide, vinylic polymer, polyphosphazene and polysiloxane.

24. (Original) The spinal nucleus implant according to claim 19 wherein said inner core is adherent to and connected to said outer jacket.

25. (Original) The spinal nucleus implant according to claim 20 wherein said reinforcing element is more deformable in axial direction than in lateral direction under axial stress.

26. (Original) The spinal nucleus implant according to claim 20 wherein said reinforcing element has a general shape selected from the group consisting of helix, ring, elipsoid, cylinder and bellows.

27. (Original) A surgical implant procedure for replacing at least a portion of nucleus pulposus tissue removed from a spinal disc of a living vertebrae to restore function of said spinal disc and related vertebral joint, which comprises:

a) creating a spinal nucleus implant in the form of an anisotropically swellable, biomimetic xerogel plastic, having a two phase structure with a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, said xerogel plastic being capable of anisotropic expansion by rehydration into an inherent shape in which it has a relaxed polymer network in a state of full hydration, and being capable of osmotic movement of liquid

therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state said anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and minimal swelling or suppressed swelling in horizontal planes;

b) surgically removing at least a portion of nucleus pulposus tissue from a spinal disc of a living vertebrae to create a cavity; and,

c) implanting said spinal nucleus implant into said nucleus pulposus cavity in an at least partially hydrated state.

28. (Original) The surgical implant procedure according to claim 27 wherein said spinal nucleus implant, in said fully hydrated state, has volume substantially larger than volume of said cavity vacated by the removal of nucleus pulposus tissue.

29. (Original) The surgical implant procedure according to claim 27 wherein said spinal nucleus implant, in said fully hydrated state, has a cross-section area substantially equivalent to the cross-section area of said cavity vacated by the removal of nucleus pulposus tissue, and height substantially larger than the height of said cavity, the "height" being the dimension substantial parallel with the spinal axis and "cross-section area" being the area lateral to the spinal axis.

30. (Original) The surgical implant procedure according to claim 27 wherein said xerogel plastic swells in situ substantially more in the direction of the spinal axis than in lateral direction.

31. (Original) The surgical implant procedure according to claim 27 wherein said xerogel plastic is implanted in an anisotropically dehydrated state in which its volume is less than 50% of the volume of said cavity vacated by the removal of nucleus pulposus tissue.

32. (Original) The surgical implant procedure according to claim 31 wherein said xerogel plastic in its anisotropically dehydrated state has the shape optimized for insertion into the cavity through a small incision in the annulus fibrosus, said shape being an approximate shape of a cylindrical body.

33. (Original) The surgical implant procedure according to claim 31 wherein said anisotropically dehydrated state is achieved by anisotropical deformation of said xerogel.

34. (Original) The surgical implant procedure according to claim 33 wherein said anisotropical deformation is achieved by heating the xerogel above its glass transition temperature, exposing it to deforming stress in a selected direction, and cooling it down under its glass transition temperature while still exposed to said deforming stress.

35. (Original) The surgical implant procedure according to claim 33 wherein said anisotropical deformation is achieved by forming said xerogel by drying the hydrated swellable plastic under a restraining stress, preventing shrinking of xerogel in one or more selected directions.

36. (Original) The surgical implant procedure according to claim 35 wherein said restraining stress is an external stress caused by applying pressure in axial direction during the dehydration process.

37. (Original) The surgical implant procedure according to claim 35 wherein said restraining stress is created by the presence of internally embedded structure preventing the shrinking in the direction lateral to the axis.

38. (Original) The surgical implant procedure according to claim 27 wherein said hydrated implant is under axial stress substantially more deformable in axial direction than in lateral direction.

39. A spinal disc implant which comprises an implant member dimensioned for positioning in a cavity defined between adjacent vertebrae, the cavity defining a first height, the implant member comprising a swellable plastic, whereby upon at least partial hydration of the implant member, the implant member undergoes anisotropic expansion and has a capacity to swell to a second height which is greater than the first height .

40. A spinal disc implant according to claim 39 wherein the cavity defined between the adjacent vertebrae is the disc space.

41. A spinal disc implant according to claim 39 wherein the first height and the second height are measured along a vertical axis and the implant member further defines a horizontal axis and a length extending along the horizontal axis, wherein the capacity to swell to a second height is greater than the relative swelling capacity of the length by at least 25%.

42. A spinal disc implant according to claim 50 wherein the relative swelling capacity of the implant member defines a cross-section area which is substantially equivalent to the cross-section area of the cavity which has been vacated by removal of nucleus pulposis tissue of a spinal disc.

43. A spinal disc implant according to claim 42 further comprising a reinforcing member which assists in limiting the increase in cross-section area of the implant member.

44. A spinal disc implant according to claim 43 wherein the reinforcing member is in a form selected from the group consisting of knitted structure, metal spring and helically wound fiber.

45. A spinal disc implant according to claim 39 wherein the swellable plastic is a hydrogel.

46. A spinal disc implant according to claim 39 wherein the implant member has a water content of more than 70% by weight.

47. A spinal disc implant according to claim 39 wherein the implant member is in the form of a xerogel which is dimensioned and configured for insertion through a small incision in an annulus fibrosus.

48. A spinal disc implant according to claim 41 wherein the volume of the implant member fully swelled in body fluid at body temperature is at least 5% larger than the volume of the cavity into which the implant is implanted.

49. A spinal disc implant according to claim 41 wherein the implant is capable of assuming three configurations:

(i) an inherent configuration assumed upon full hydration of the implant, the inherent configuration having a cross-section area which is substantially equivalent to the cross-section area of the cavity, wherein the cavity is formed by removal of nucleus pulposis tissue of a spinal disc; and the inherent configuration defining the second height;

(ii) an insertion configuration assumed upon at least partial dehydration of the implant which has a smaller volume than the inherent configuration, the insertion configuration dimensioned and configured to facilitate insertion through a small incision in an annulus fibrosus; and

(iii) an indwelling configuration assumed upon insertion of the implant into the cavity vacated by removal of nucleus pulposis tissue of a spinal disc, the indwelling configuration having a cross section area which is substantially equivalent to the cross-section area of the inherent configuration, and a height which is less than the height of the inherent configuration and which is determined by and which corresponds to the height of said cavity whereby positive swelling pressure is generated by the implant between the adjacent vertebrae to increase vertebral separation.

50. A spinal disc implant according to claim 41 wherein the implant further defines a transverse axis to the vertical axis and perpendicular to the horizontal axis, the horizontal axis and transverse axis defining a plane which is transverse to the vertical axis, the implant having a width which is measured along the transverse axis, wherein the implant has a capacity to expand the width along the transverse axis which is at least 25% greater than the expansion of length measured along the horizontal axis.

51. A spinal disc implant according to claim 50 wherein the length of the implant does not expand along the horizontal axis.